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Subcommittee on Health
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What It Means for Jobs, Innovation and Patients"
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Introduction

My name is Elisabeth George, and I represent Philips Healthcare as Vice President of Global Government Affairs, Regulations and Standards. I want to start by thanking Chairman Pitts and Ranking Member Pallone for your holding today's hearing. I also want to thank you for your particular interests in medical innovation and for leading a policy discussion on what the flaws are in our system and how we can work together to collectively improve it during this reauthorization of the medical device user fee program. It is clear to me that we all share the goal of getting safe and innovative products to U.S. patients more quickly.

Philips Healthcare's current activities are organized across four businesses: Imaging Systems (X-ray, computed tomography (CT), magnetic resonance (MR) imaging, nuclear medicine and ultrasound); Patient Care and Clinical Informatics (patient monitoring, hospital respiratory systems, children's medical ventures, cardiac care systems, healthcare informatics and image management services); Home Healthcare Solutions (sleep management and respiratory care, medical alert systems, remote cardiac services, remote patient management); and Customer Services (consultancy, clinical series, education,

equipment financing, asset management and equipment maintenance and repair). Especially because of our diverse portfolio, we have appreciated your steadfast support in ensuring the access to medical technology and particularly imaging and its appropriate use for patients. I am confident that today's hearing will serve to further ensure patient access to safe and effective technologies.

I have worked for Philips Healthcare for more than 15 years and have managed strategic planning and technical aspects for global affairs, regulations and standards including quality, reliability, safety, product security, privacy and sustainability compliance for Philips Healthcare business around the world. My responsibilities include supporting the organization in ensuring worldwide compliance and continual improvement in product submissions, post-market surveillance, product reliability improvement, International standards and regulations, quality systems (ISO13485, 21CFR), and environmental management system (ISO14001 & OHSAS 18001) for Philips products in the area of Home Healthcare, Patient Monitoring Systems, Healthcare Informatics, External Defibrillators, Cardiographs, X-Ray Systems, MR Systems, CT Systems, Nuclear Medicine Solutions and Generators.

I have also served on multiple FDA advisory panels though the years and have most recently represented the medical imaging industry during the Medical Device User Fee Agreement negotiations with the FDA.

As an industry negotiator, I am pleased to talk with Congress today about our first successful step in the process to final reauthorization: the agreement in principle between medical device industry representatives and the FDA. We believe that this agreement will facilitate improved transparency and consistency from the agency leading to better outcomes and more timely access for patients in need of safe and effective medical devices.

After negotiating for more than a year, the FDA and the medical device

manufacturing industry have successfully come to this agreement in principle, which we feel is balanced and fair to all stakeholders. We hope that the balanced approach taken by this package will lead to a timely proposal to Congress on reauthorizing and improving the Medical Device User Fee Program.

The goal of this agreement is to ensure timely patient access to safe and effective treatments and diagnostics. Although the agreement is not formally proposed to Congress until it receives full Administration approval and the FDA completes its public commenting process, the package as negotiated includes commitments from the Agency that will improve the device review program through additional predictability, transparency, and accountability. In a time of tremendous advances in medical technologies, the agreement enables the industry to bring innovative, life-saving technologies to market faster, so that patients receive the highest quality care.

What Medical Devices Mean to Patients

Philips is a manufacturer of a diverse range of medical devices, from patient monitoring systems that can be used in the home to advanced medical imaging equipment for use in a hospital or physician office setting. These technologies are critical to patient care, and we are committed to ensuring that the FDA device review process works effectively. An effective and efficient process not only benefits us by ensuring our products get to market, but it also prevents patients from being left unable to access the device that helps them rest comfortably at home or the advanced imaging technology that detects their cancer early, when it is most treatable.

The devices we produce are central to patient care. For example, the *New England Journal of Medicine* declared that medical imaging is one of the top "developments that changed the face of clinical medicine" during the last millennium – as important as anesthesia and antibiotics.[i] Physicians who care for patients each day have echoed that

assessment and have ranked MRI and CT technology as the most valuable medical innovations in the last 30 years.[ii] Indeed we know that the term "exploratory surgery" is all but obsolete due to the advancements made in medical imaging. Wait times to diagnosis and treatment have been shortened, allowing Americans to put an illness or injury behind them and get back to their lives and their families more quickly than ever before.

Additionally, in the field of medical imaging, Philips has focused on patients are exposed to the lowest radiation dose possible, while giving physicians an image resolution that allows them to make an accurate diagnosis. Philips and the entire medical imaging industry are dedicated to the ALARA dose management principle, which stands for "as low as reasonably achievable" Medical imaging manufacturer have produced groundbreaking innovations to make this principle a reality. As a result, today's medical imaging technologies make imaging procedures safer than ever.

These technologies are critical for patient care and diagnosis, and give patients and physicians peace of mind. Because these technologies are so important to patients and central to physician standards of care, we have worked with the FDA over the years on ways to improve the timeliness, consistency and transparency of the pre-market approval process. When that process is broken, it not only stifles innovation, but also patient care.

History of MDUFA Negotiations

As you may know, medical device user fees arose following widespread concerns with the lengthy FDA approval time and the associated harm that this delay had on innovation and patient care. Congress initially gave FDA the authority to collect medical device user fees in 2002. The original negotiation between the FDA and industry established user fees for premarket applications (PMAs), premarket notifications (510(k)s), and other types of requests to market medical devices. The original negotiated agreement listed specific performance goals for FDA for premarket device reviews only.

Since that time, that basic structure has remained. During the last negotiation, the Medical Device User Fee and Modernization Act (MDUFMA), in 2007, industry agreed to increase fees for additional performance improvements from the FDA.

The explicit goal of the device user fee program has been to achieve more timely clearance of safe and effective devices by providing FDA with supplemental funds to independently evaluate applications. In fact, the 2007 law specifically states that "the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications"[iii].

However, despite clear Congressional intent, FDA performance has unfortunately declined steadily over the past several years. For example, in FY2006, FDA took an average of 105 calendar days to make a final decision on a 510(k) submission. That number increased to 154 calendar days in 2009 despite the fact that user fees had increased by more than half over the same period. Concern with the decline in FDA device approval timeliness has been an overarching concern for industry during the years leading up to our most recent negotiation period. Our goal in negotiating this agreement was to reverse this downward slide and ensure value for our user fee investment for both patients and innovators.

Highlights of the MDUFA Agreement in Principle

As you may have seen in the published minutes from the official negotiation meeting with the FDA and industry negotiators in January 31st, the negotiators have put in place what we believe is a strong and fair agreement in principle. At this point that agreement needs to receive further review and approval by the Administration.

The new agreement negotiated by FDA and industry would make key improvements to the review program while providing the Agency with the resources it needs to expedite the pre-market process. Under the agreement, industry would provide a total of $595

million to FDA in user fees from Fiscal Year 2013 to Fiscal Year 2017. When combined with Congressional appropriations, this resource level will enable FDA to substantially increase the resources it can dedicate to the review process. It will be incumbent upon the FDA to ensure that these employees are qualified and quickly and thoroughly trained to ensure the Agency meets the goals set forth in the tentative agreement.

Ensuring Patient Access to Innovative Technology

The increase in resources to the agency under this agreement corresponds to a more timely approval process, which will benefit patients and the manufacturers who develop these innovative technologies. The agreement includes several new quantitative goals to hold FDA accountable for its commitment to reducing review times.

Total Time Goal: For the first time, FDA has agreed to establish a "total time" goal, which will hold FDA accountable for the length of time— importantly, in clearly understandable calendar days—between the submission of a device application and a final review decision. In prior agreements, performance goals were based solely on "FDA days", which allow the Agency to "stop the clock" and therefore technically meet the goals without expediting reviews. The total time goal will ensure that both the FDA, industry, and all other stakeholders understand the time it takes to bring a new or improved technology to market. This goal will hold both the FDA as well as industry to a new standard of accountability, as each party works to improve efficiencies to ensure patient access to innovative devices is not unnecessarily delayed.

Substantive Interaction Goal: Another new goal, the "substantive interaction goal", will require FDA to initiate a productive discussion of Agency concerns between reviewer and manufacturer early in the review process. This early interaction is invaluable in helping manufacturers understand the Agency's questions or concerns about a device and improving industry responses.

510(k) Approval Time Improvements: As you may know, most of the devices produced by Philips Healthcare are approved through the 510(k) program. Over 90 percent of all medical devices entering the market in the United States go through the 510(k) process. This pathway is absolutely essential, as it gives patients access to important incremental improvements in medical device technology. Meanwhile, this process also allows increased investment in research and development by manufacturers—producing exciting new technological developments.

Fortunately, the agreement in principal between FDA and industry strengthens and reforms existing 510(k) program review goals in very important ways. Under the existing user fee goals, FDA is expected to make a final decision on 90% of 510(k) submission decisions within 90 days. The new agreement would improve the Agency's performance goal to 95% in 90 days for 510(k) decisions by FY16. The new agreement also eliminates the existing and counter-productive 150 day performance goal, replacing it with a process that encourages a meaningful discussion between FDA and the manufacturer on every stalled submission. This new process will require extensive management involvement in delayed applications, which will better enable Agency managers to respond to recurring process problems. In addition, this change also avoids the negative consequence of the existing metric, which unintentionally creates a perverse incentive for reviewers to delay final decisions for reviews that miss the initial 90 day performance goal.

FDA's commitment to meeting these new and improved review time goals will expedite the review process and help ensure patients have access to innovative medical devices.

Improving Predictability, Transparency, & Accountability

The agreement also works to ensure an improved review process that is more predictable and transparent for manufacturers, patients, and other stakeholders.

Enhanced Clarity in the Pre-submission Process: The agreement requires FDA to enhance its pre-submission meeting process to provide more robust feedback to a manufacturer prior to a submission. The improved process prevents FDA from changing the requirements communicated at this stage, barring the development of important new issues that materially affect safety or effectiveness.

Enhanced Guidance Development: The agreement also requires FDA to dedicate resources to developing guidance documents for industry and Agency staff with the goal of ensuring both the reviewer and the manufacturer understand the FDA's current thinking on important questions of safety and effectiveness.

Detailed Performance Reports: Under previous MDUFA agreements, often FDA has been slow to provide industry and other stakeholders with the information necessary to judge the Agency's performance and provide constructive input on how the Agency could improve. The MDUFA III agreement requires FDA to increase transparency by publishing more detailed performance reports. This information will help industry identify areas where FDA and manufacturers can work together to remove obstacles to effective and timely device reviews.

Independent Assessment of Performance: Perhaps one of the most valuable new items for improving transparency and accountability is that the FDA has agreed to an independent assessment of its management of the device review process, which will provide an unbiased analysis of how FDA can improve its performance. The FDA has committed to respond to this audit with a corrective action plan that addresses problem areas and improves the Agency's management of both the taxpayer dollars and industry user fees that fund the device review program.

Conclusion

I can't overstate the importance of an effective and efficient medical device pre-

market review program. That's why I greatly appreciate this Committee's demonstrated interest in improving the review process in the United States, to ensure innovative companies can continue to advance innovation in medicine.

Philips Healthcare employs over 15,000 hardworking Americans in cities and towns across America—and we are just one company in a global industry. One recent study found that the American medical device industry employs over 422,000 American workers, with jobs in every state.

I don't think our industry can take a single job for granted in times like these. Unfortunately, the current system's lack of predictability and the trend of increased review times have combined to force many investors to put their capital into projects in Europe—where device reviews are often significantly shorter than in the United States. This trend has raised concerns across the industry of where the American medical device industry is headed without improvements to the regulatory environment in the U.S. like those included in the MDUFA III agreement.

That's why we simply can't afford to delay reforms that expand patient access to safe and effective medical devices while fostering the kind of innovation that will improve care and reduce costs. In fact, I believe it's more important than ever that Congress do everything possible to encourage high-tech 21st century industries—like medical device manufacturing—that will continue to create the jobs necessary to grow the U.S. economy.

We are very appreciative of Members of this Committee who have held a series of hearings and introduced a number of bills in an effort to respond to these concerns and improve the FDA review process for medical devices. I believe that all our efforts have been constructive. We certainly can't afford to move in the opposite direction and make it more difficult for patients to access devices the FDA deems safe and effective.

Thank you for your consideration of these important issues. As the legislative

process moves forward, we at Philips Healthcare, along with our industry partners, look forward to continuing to work with Congress and the Administration to ensure patients are guaranteed timely access to medical technologies. We believe that timely access will continue to improve quality of life for millions of Americans and patients around the world. I thank you again for this invitation to testify.

[i] The Editors. "Looking back on the millennium in medicine." *New England Journal of Medicine (NEJM)*, 342: 42-49, 2000.
[ii] Fuchs VR and Sox HC Jr. "Physicians' Views of the Relative Importance of Thirty Medical Innovations." *Health Affairs*, 20(5): 30-42, 2001.
[iii] P.L. 110-85, Sec. 201(c)